REMARKS

This is a full and timely response to the Office Action mailed October 3, 2008, submitted concurrently with a two month extension of time to extend the due date for response to March 3, 2009.

By this Amendment, claim 4 has been amended to more particularly define the present invention. Thus, claims 1-11 are currently pending in this application. Support for the claim amendments can be readily found variously throughout the specification and the original claims.

In view of these amendments, Applicant believes that all pending claims are in condition for allowance. Reexamination and reconsideration in light of the above amendments and the following remarks is respectfully requested.

Rejections under 35 U.S.C. §103

Claims 1 and 2 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown et al. (U.S. Patent No. 3,837,376) in view of McEwen et al. (U.S. Patent No. 5,308,506). Further, claims 3 and 6 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown et al. (U.S. Patent No. 3,837,376) in view of McEwen et al. (U.S. Patent No. 5,308,506) and further in view of Krug (U.S. Patent No. 2,833,281). Still further, claims 4 and 5 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown et al. (U.S. Patent No. 3,837,376) in view of Faulkner et al. (U.S. Patent No. 5,624,554). Lastly, claims 7-11 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Brown et al. (U.S. Patent No. 3,837,376) in view of Kasai et al. (U.S. Patent No. 5,213,765). Applicant respectfully traverses these rejections.

To establish a *prima facie* case of obviousness, the cited references, in combination, must teach or suggest the invention as a whole, including all the limitations of the claims. Here, in this case, Brown et al., in combination with the other cited references, McEwen et al. Krug, Faulkner et al. and/or Kasai et al., fails to teach or suggest all of the limitations of the claims with particular emphasis on the limitations "*a filter member provided in the sample collection part, for filtering the sample collected in the sample collection part*", "*at least one vane provided on the side*

of the needlepoint of the communication needle", and "*wherein the vane has a shape that approaches the communication needle as they extend to their tip ends*".

Given Applicant's review of Brown et al., McEwen et al., Krug, Faulkner et al., and Kasai et al., Applicant believes that there are clear distinctions between the present invention and the cited references.

The present invention is directed to (1) methods for filtering a sample using a sample collecting container, (2) a jig and (3) a sample collecting container. The sample collecting container is capable of not only securely completing filtration of a sample through a filter member using a reduced pressure in the container, but also eliminating an operation that may cause infection such as removing a plug member so as to complete the filtration. The sample collecting container includes a sample collection part, a filter member and a sample storage part.

Please note that the filter member is provided in the sample collection part, for filtering the sample collected in the sample collection part. The filter member is formed of an appropriate filter material for removing solid substances in the sample (see paragraph [0038] of the present patent application publication 2006/0199275). The filtration stops when the pressures of the upside space and the downside space of the filter member reach equilibrium in sample collecting container. A jig is used to establish communication between the interior space of the sample collection part and the atmosphere, whereby a pressure difference is given between the internal space of the sample collection part and the internal space of the sample storage part. Consequently, this pressure difference allows for progression of the filtration again.

In contrast to the present invention, Applicant believes that Brown et al. does not teach or suggest the filter member of the present claims. Brown et al. only teaches a method and apparatus which provide a new and improved method of collecting serum and a new and improved self sealing, serum collecting tube, where the tube may be directly filled from centrifuged specimen tubes with collected blood serum.

In the Office Action (see page 3, item 6 of the Office Action), the Examiner stated "*[W]ith regards to claim 1, Brown et al. teach a method of filtering a sample comprising a sample collection part for storing a sample (figure 1 #10), a plug member (figure 1 #18), a filter member (figure 1 #15), a sample storage part (figure 1 1#15)*. Hence, the Examiner has set forth that the

filter member in the present invention corresponds to a clear collection tube (figure 1 #15) disclosed in Brown et al. However, Applicant disagrees with the Examiner's conclusion because Applicant believes that the clear collection tube lacks the ability to filter the sample.

Unlike the apparatus in the present application, the serum collection tube in Brown et al. does not filter any collected sample. Rather, it aims to remove blood serum from the centrifuged specimen tube by securely trapping the blood serum within the collection tube (see column 3, lines 31-34, of Brown et al.). Even before the apparatus is utilized, blood samples are centrifuged in accordance with well known procedures (see column 2, lines 31-34, of Brown et al.). Therefore, the filtering is not needed for this apparatus to work. As a part of the apparatus, the clear collection tube does not remove solid substances in the sample. Rather, it acts to only store the blood serum without disturbing the clotted matter (see column 3, lines 40-45, of Brown et al.). Therefore, the filter matter in the present invention is not the same as the clear collection tube of Brown et al.

With regards to the teachings of McEwen et al., the Examiner has cited this reference as teaching a *method of separating a sample of blood wherein a plug member hermetically seals the sample container and the area around a piercing needle*. Further, the Examiner has cited McEwen et al. as teaching *a vacuum to draw the sample liquid into the tube*. However, even assuming that the Examiner is correct in this regard, McEwen et al. does not cure the deficiencies of Brown et al. as noted above.

In the Office Action (see page 4, item 9 of the Office Action), the Examiner has cited Krug as *teaching a venting needle comprising a groove extending from the needle point to an opposite end of the needle*. However, Krug teaches an axially extending groove, which as shown in Figures 1 to 3, preferably does not extend entirely through the body but rather has its base substantially in line with the axis of the same (see column 1, lines 55-59, of Krug). Thus, the groove in Krug does not extend entirely to an opposite end of the needle as the groove in the present invention (see Figures 12A and 12B of the present drawings). Therefore, Applicant believes that Krug does not teach or suggest the groove claimed in the present application.

In the Office Action (see page 4, item 11 of the Office Action), the Examiner has only cited Faulkner et al. as teaching *a collection device with a vane positioned at the base of the projection within the device*. Faulkner et al. teaches a collection and transfer device which contains

a shank that includes agitator vanes 21 and 22 for collecting sample (see column 3, lines 55-65, Faulkner et al.). The Examiner equates the agitator vanes 21 and 22 to a vane in the present application. However, Applicant disagrees with the Examiner's conclusion in this regard.

In contrast to the present invention, the agitator vanes in Faulkner et al. are used for mixing a sample within the collection vessel (see column 2, lines 37-39, of Faulkner et al.). Therefore, they are spread out from a spoon portion (20) of the shank (see Figure 1 of Faulkner et al.). However, the vanes in the present invention are designed to have a shape that approaches the communication (i.e. hollow) needle as they extend to their tip ends. Based on such a shape, the piercing resistance at the time of piercing the plug member with the communication needle is lowered (see paragraph [0048] of the present patent application publication). Therefore, such "far out" extended shape of the agitator vanes in Faulkner et al. teaches away from the purpose of the vanes in the present invention since the vane shape in Faulkner would result in large piecing resistance and leave a large mark on the plug member. Therefore, Applicant does not believe that the agitator vanes 21 and 22 of Faulkner are equivalent to the vanes of the present invention.

Nevertheless, to emphasize the above noted distinction between the vanes of the present invention and that of Faulkner, Applicant has amended claim 4 to recite that "*the vane has a shape that approaches the communication needle as they extend to their tip ends.*"

Further, aside from this distinction between the vanes of Faulkner et al. and the vane of the present invention, Brown et al. does not teach a plug member hermetically sealing the opening (see Office Action page 3, item 6). Therefore, Applicant believes that even if Faulkner et al. does teach the vanes in the present application, it would not cure this deficiency in Brown et al.

Lastly, in item 14 on page 5 of the Office Action, the Examiner has only cited Kasai et al. as teaching *a blood collection tube comprising a hermetically sealed plug member and a sealing member on the outer surface of the plug member*. Kasai et al. teaches a blood collection tube which can carry a predetermined quantity of an anticoagulant on a support surely and easily. The blood collection tube in Kasai et al. comprised a bottomed tube whose open end is hermetically sealed by a plug. However, despite such teachings, Applicant believes that Kasai et al. does not overcome the deficiency (i.e. filter) in Brown et al. noted above.

Thus, for these reasons, withdrawal of the present rejections is respectfully requested.

CONCLUSION

For the foregoing reasons, all the claims now pending in the present application are believed to be clearly patentable over the outstanding rejections. Accordingly, favorable reconsideration of the claims in light of the above remarks is courteously solicited. If the Examiner has any comments or suggestions that could place this application in even better form, the Examiner is requested to telephone the undersigned attorney at the below-listed number.

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